



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,822	12/31/2003	John Pafford	1842-0029	9366
28078	7590	04/19/2007	EXAMINER	
MAGINOT, MOORE & BECK, LLP			HOFFMAN, MARY C	
CHASE TOWER			ART UNIT	PAPER NUMBER
111 MONUMENT CIRCLE			3733	
SUITE 3250				
INDIANAPOLIS, IN 46204				
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/19/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/749,822	PAFFORD ET AL.
	Examiner Mary Hoffman	Art Unit 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-8,15-20 and 31 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-8,15-20 and 31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/31/2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

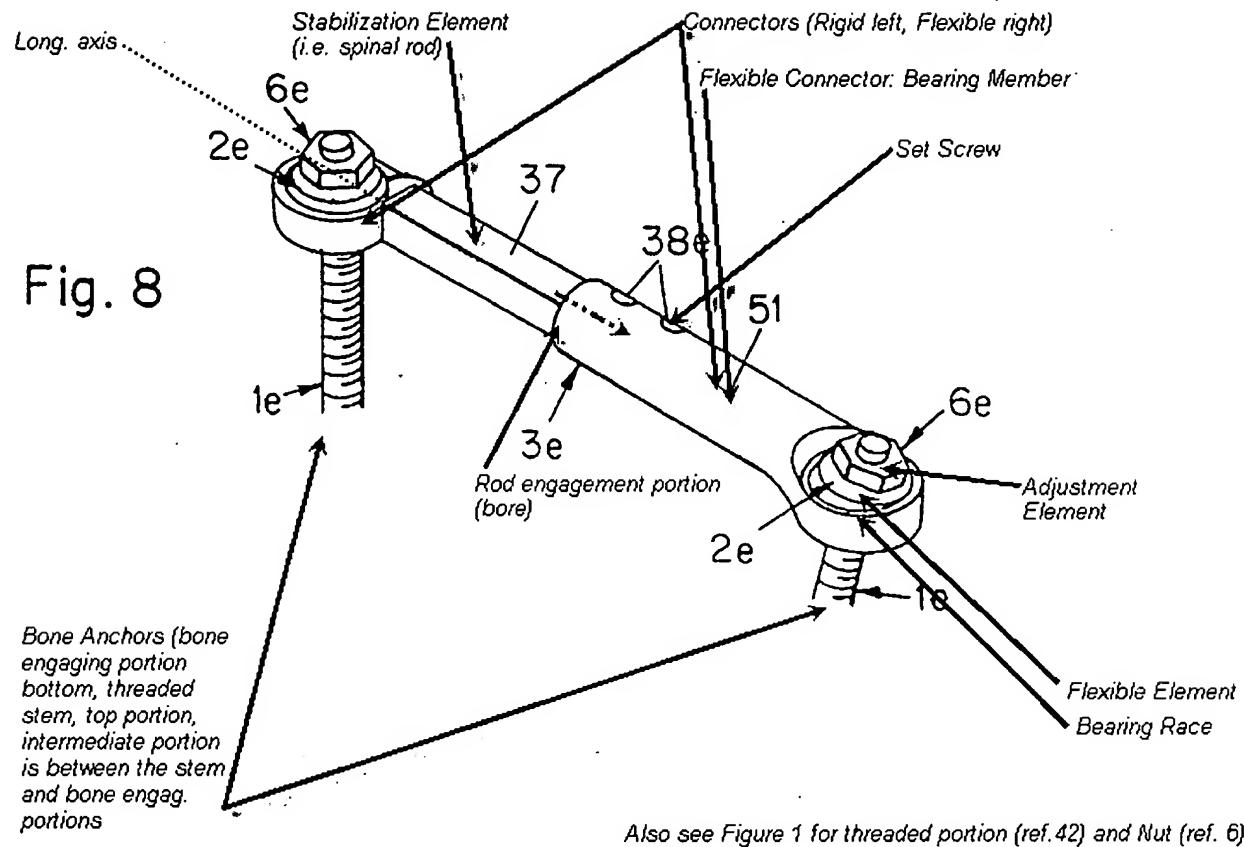
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlapfer et al. (U.S. Patent No. 5,501,684).

Schlapfer et al. disclose a dynamic stabilization system for stabilization comprising a stabilization element (FIG. 8, ref. 37) capable of spanning between at least two vertebrae and defining a longitudinal axis along the length of the element: at least two bone anchors (ref. 1e), each having a bone engagement portion (lower half); and at least two connectors (see FIG. 8, attachment mechanisms fixing ref. 1e to the stabilization element, ref. 37) for connecting a corresponding one of the bone anchors to the stabilization element, at least one connector including; a bearing member (ref. 51) attached to the stabilization element; a flexible element (ref. 2e) supported within the bearing member with the bone anchor extending through the flexible element, the flexible element contacting the bearing member substantially along the longitudinal axis of the stabilization element to permit relative pivoting between the corresponding bone anchor and the stabilization element; and an adjustment element (ref. 6e) for adjusting the flexibility of the flexible element. The stabilization element includes an elongated

spinal rod, the bearing member is a rod end bearing including a rod engagement portion; and the flexible element is a bearing element of the rod end bearing. The bearing element is received within a bearing race (integral with ref. 51, the surface along circumference of the bore in which ref. 2e is placed) of the rod end bearing; and the adjustment element is arranged to compress the bearing element within the bearing race. The rod engagement portion includes a bore for receiving a portion of the spinal rod therein and a set screw (ref. 38e) for clamping the spinal rod within the bore. The at least one of the bone anchors includes a stem having a threaded portion (see FIG. 1, ref. #42); the flexible element includes a bore for receiving the stem therethrough; and the adjustment element includes a nut engaging the threaded portion and arranged to compress the flexible element as the nut is threaded onto the threaded portion. The at least one of the bone anchors includes an intermediate portion (see FIG. 1, ref. 11) between the stem and the bone engagement portion, the intermediate portion configured to support the flexible element so that the flexible element is compressed between the intermediate portion and the nut when the nut is threaded onto the threaded portion. Another of the connectors is configured to substantially rigidly connect one of the bone anchors to the stabilization element (see FIG. 8, left side). The at least one connector including a unitary bearing member. The flexible bearing element mounted within the bearing race. The flexible element has a substantially spherical outer surface; and the bearing race defines a substantially spherical inner surface engaging the outer surface of the flexible element.

Schlapfer et al. (Patent 5,501,684)



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlapfer et al. (U.S. Patent No. 5,501,684).

Schlafper et al. discloses the claimed invention except for the bearing race being mounted within the bearing member (thus indicating that the bearing race is not integral with the bearing member). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bearing race not being integral with the bearing member, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Response to Arguments

Applicant's arguments filed 01/23/2007 have been fully considered but they are not persuasive.

Applicant argues that the Schlafper reference, Patent No. 5,501,684, discloses neither the "flexible element...to permit relative pivoting between said corresponding bone anchor and said stabilization element" nor the "adjustable element for adjusting the flexibility of said flexible element" of claim 1. The examiner respectfully disagrees, and maintains that element 2 in Schlafper corresponds to Applicants' claimed "flexible element" and that element 6 in Schlafper corresponds to Applicants' claimed "adjustable member." While the examiner notes that element 2 of Schlafper contacts the borehole 31 of the connecting element 3 and is tightened by element 8 to clamp the two components (element 2 and connecting element 3) together, the examiner asserts that prior to tightening with tool 8, the spherical element 2 will permit relative pivoting between the bone anchor and connecting element. Also, in col. 2, line 54, the reference

states that the spherical element is rotatable in the borehole of the connecting element. Therefore, it is the examiner's opinion that the prior art meets the claimed functional language of being able to permit relative pivoting. Furthermore, the element 2 is considered flexible because it is able to be expanded, or deformed, for example, when instrument element 8 is subsequently rotated to expand the element 2 into the connecting element 3 to lock the assembly together. Regarding Applicants' assertion that element 6/6e of Schlapfer is not an "adjustment element" as recited in claim 1, the examiner respectfully disagrees. The element 6 threaded onto the threaded end of tension element 4 operates to further secure the fixation between the conical head section 11 of the fastener 1 and the tapered bore 21 of the clamping element 2. This can be considered as "adjusting the flexibility of said flexible element" since it is preventing the element 2 from becoming loose, i.e. controlling its flexibility. Also, it is noted that "for adjusting..." is functional, and the element 6 is capable of adjusting the flexibility. For example, the nut element 6 could be used in lieu of the tool 8 to tighten the element 2 with the connecting element 3 if one so desired.

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the Schlapfer reference, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218

USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding the rejection of claims 15-20 and 31 under 103(a), the examiner is considering the interior circumferential surface of the borehole to be the integral bearing race. The examiner interior circumferential surface of the borehole allows the element 2 to rotate within (see col. 2, line 54), therefore, it would be obvious to make a non-integral bearing race, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. In response to Applicants' argument that

"once the components 1, 2 and 3 are locked together, there is no movement allowed in the Schlapfer construct. When movement is permitted in Schlapfer - i.e., before the construct is finally fixed within the spine - there is no bearing contact between the clamping element and the connecting element borehole," the examiner respectfully disagrees. As stated in col. 2, line 54, the element 2 (the clamping element) is rotatable in the borehole of element 3 (the connecting element) while being firmly seated.

The rejections are deemed proper.

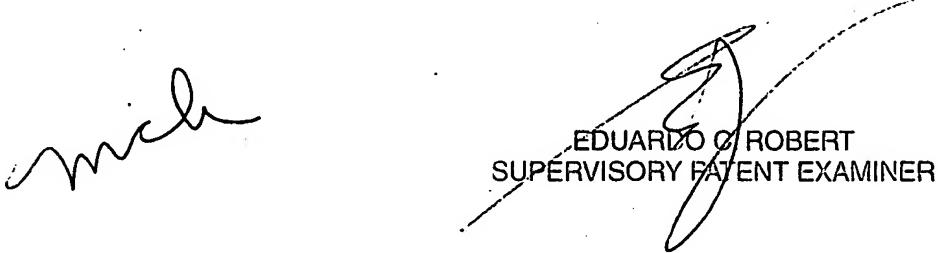
Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH

Mel